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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,267	02/14/2002	Vikas Kundra	UTSC:753US	3359
8791	7590	12/15/2005	EXAMINER	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD SEVENTH FLOOR LOS ANGELES, CA 90025-1030			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/076,267	Applicant(s) KUNDRA, VIKAS	
	Examiner Konstantina Katcheves	Art Unit 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-85 is/are pending in the application.  
     4a) Of the above claim(s) 1-15, 26-37 and 66-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18-25, 38-65 and 78-85 is/are rejected.
- 7) ☒ Claim(s) 23 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-16 and 18-85 are pending in the present application. Claims 1-15, 26-37 and 66-77 are withdrawn from consideration. Claims 16, 18-25, 38-65 and 78-85 are currently under examination.

### ***Election/Restrictions***

Applicant's election without traverse of Group III, claims 16, 18-25 and 78-85, in the reply filed on 23 September 2005 is acknowledged. Claims 1-15, 26-37 and 66-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 September 2005.

### ***Response to Amendment***

The restriction requirement mailed on 15 July 2005 was made based on the extensive amendments to the claim which rendered the rejections made in the Office action 18 June 2004 moot and necessitated the restriction requirement referred to above and also necessitate the new grounds of rejection found below. Therefore, any rejections found in the Office action mailed 18 June 2004 are withdrawn.

### ***Claim Objections***

Claims 23 and 24 are objected to because of the following informalities: These claims do not properly depend from any one of the preceding claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 18, 20, 22-24, 38, 40-43, 48, 49, 52, 53, 55-60, 65, 66, 78, 79, 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Coward et al. (PNAS Vol. 95 January 1998 pp352-357).

The invention of the instant claims is drawn to a method for detecting a recombinant G-protein associated receptor (*i.e.* a G-protein coupled receptor). The method comprising introducing a nucleic acid encoding a recombinant G-protein coupled receptor into a cell and detecting expression of the G-protein coupled receptor based on “chemical, physical or biological properties” associated with a ligand’s interaction to the receptor. Additionally, the recombinant G-protein coupled receptor is tagged with a leader peptide or signal sequence.

Coward et al. disclose the method of the instant claims. Coward et al. teach a system that detects the expression of G-protein coupled receptors *in vivo*. The method requires engineered chimeric G-protein coupled receptors (e.g. Ro1 and Ro2 derived from the  $\kappa$  opioid receptor). See abstract and page 352, column 2, last paragraph. The receptors are tagged with a FLAG epitope or a hemagglutinin epitope and a signal peptide. Plasmid constructs encoding these recombinant receptors are transfected into CHO cells. CHO cells were plated onto 96 well microplates and interactions between the G protein coupled receptor and ligand were read using a fluorometric imaging plate reader (FLIPR). See page 353, column 1, first paragraph and bridging paragraph.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 18-25, 38-65 and 78-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." A specification must convey to one of skill in the art

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that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words,

structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."

See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The invention of the instant claims is recites the genres of recombinant seven transmembrane G-protein associated receptors, recombinant somatostatin receptors, somatostatin type 2 receptors, and mutated somatostatin type 2 receptors. Each of these genres represents a broad class which encompasses a wide range of species for which Applicant has failed to adequately describe to appraise one of skill in the art that Applicant had possession of these broad genres at the time of filing.

The specification does not disclose a representative number of species of the broad genres claimed to provide adequate description. For example, the claims are drawn to any recombinant G-protein coupled receptor and/or any recombinant or mutant somatostatin or somatostatin type 2 receptors, yet the specification fails to disclose a representative number of species. Furthermore, the recombinant G-protein associated and somatostatin receptors envision truncations and deletions which are not described in the specification. The specification fails to disclose the sequences of these receptors, yet the claims and specification recite that a specific truncation of the sequences is

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found at amino acid 314. Without the disclosure of specific sequences it would be impossible for one of skill in the art to envision the broad genres claimed by Applicant.

Thus, the specification does not describe the complete structure of a representative number of species. The specification also fails to describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent such teachings and guidance, the specification does not describe the claimed genres in such full, clear, concise and exact terms so as to indicate that Applicant had possession at the time of filing of the present application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64 and 81-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims state that amino acids C-terminal to amino acid 314 of the SSTR2A protein are deleted. Without a sequence of reference, this claim is vague and indefinite.

### ***Conclusion***

Any rejections not repeated herein are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



**JAMES KETTER**  
**PRIMARY EXAMINER**